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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,674	07/10/2003	Carl A. Forest	13194.102US	2594

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EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,674	FOREST, CARL A.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt of Information Disclosure Statement filed 4/1/05 is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.
Claims 2-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition included with salad dressing base, which can comprise guarana, ma huang, dressing base and other ingredients, does not reasonably provide enablement for a fat blocker, carbohydrate blocker, appetite suppressant, metabolizer, weight loss stimulant and nutrient partitioning modulator. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.
Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986)

at 547 the court recited eight factors:

1) the nature of the invention,

2) the quantity of experimentation necessary,

3) the amount of direction or guidance provided,

4) the presence or absence of working examples,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

The claimed invention relates to weight loss salad dressing, which encompasses any fat blocker, any carbohydrate blocker, any appetite suppressant, any metablolizer, any weight loss stimulant, and any nutrient partitioning modulator. Various ingredients of the kinds mentioned above having various different degrees of effects and different dosages. Given the great diversity between various ingredients (fat blocker, carbohydrate blocker, appetite suppressant, etc.), the unpredictability of losing weight has a number of facets, as the potency, amount used of the ingredient and its effect related to other ingredients in the composition. In addition, the specification does not

offer sufficient guidance to the amount of the salad dressing used in each meal and the number of times to be used daily. Note that a salad is not a regular essential component of each meal normally.

furthermore the different ingredients as claimed are general categories which broad members may end up by interacting or overlapping with each other causing an undesirable degree of effects.

2. The breadth of the claims

The claims are very broad and inclusive of many categories which includes any fat blockers, carbohydrate blockers, etc. Also, the claims are so broad that they do not include an active agent thereof. Clearly, the composition is only an expectation to weight loss, in which, categories used are known to have the desirable effect.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction for ascertaining, which ingredient of these categories is used in the composition and which is not. It also does not provide enough guidance for which of the recited ingredients (as guarana, hydroxycitric acid etc.) has an individual effect or multiple effects desired.

4. The quantity of experimentation: In the instant case, there is a substantial confusion in using broad categories without limiting each category to one or more ingredients that can be used for the purpose of weight loss and would be convenient as an ingredient in a salad dressing. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to overcome this confusion. In order

to utilize the recited categories as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation to try every and each fat blocker, appetite suppressant, metabolizer, etc. to ensure which ingredients are audible for a salad dressing, and which will give the desired effect without interacting positively (enhancing the effect) or negatively (contradicting the effect) with the other ingredient.

5. The relative skill of those in the art: the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

2. Claims 2-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite a fat blocker, a carbohydrate blocker, appetite suppressant, metabolizer, weight loss stimulant and nutrient partitioning modulator that are not further described by the specifications of the instant invention or further limited by the claims. These categories as recited are very broad and each category comprises tens of ingredients that will need a skilled man in the art to envision what to include or exclude in a salad dressing to accomplish loosing weight in a subject.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sundram et al.

US 20020034562 (Sundram).

Sundram teaches a method and composition for increasing the HDL concentration and the HDL/LDL concentration ratio in human serum. The composition can be used in dressing salads and causes weight loss (0030, 0092).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundram et al. US 20020034562 in view of McCleary US 6,579,866 (McCleary), Hastings US 5626849 (Hastings), and further in view of Dente US 6277396 (Dente).

Sundram suggested the use of a weight reduction composition on a salad dressing. It is noted that Sundram did not disclose a specific salad dressing base, however, the kinds of salad dressing bases recited in instant claim 12 are all known to any artisan who work in the nutrition field.

Sundram is deficient in disclosing the instant weight loss composition.

McCleary teaches composition and method for modulating nutrient partitioning to increase oxidation of fat and promote increased storage of glycogen is composed of hydroxycitric acid, carnitine, biotin, a gluconeogenic substrate, and, optionally, one or

more of chromium, conjugated linoleic acid, coenzyme Q10, eicosapentaenoic acid, pyridoxine, alpha-lipoic acid, magnesium, and gymnema sylvestre (gymnemic acid), see abstract. The amounts and ratios of ingredients disclosed by McCleary are similar, within or overlapping with the amounts and ratios disclosed by the instant application in claims 20, 21 and ratios in claim 16 (see tables 1, and 2). McCleary also discloses that In a preferred embodiment, the method of this invention further involves following on a daily basis a dietary regimen wherein the carbohydrate content is less than about 50% of the total daily caloric intake, the glycemic index is less than about 60 , and the protein content is at least about 20% of the total caloric intake (col. 3, lines 40+).

The two references do not disclose the use of guarana and/or mahuang.

Hastings discloses a dietary supplement that can be used as a weight loss composition. The composition comprises chromium, L-carnitine, gamma-linolenic acid, (-) hydroxycitric acid, choline, inositol, antioxidants and herbs. Hastings also disclosed that it is known in the art that Smartbody (by Life Extension) provides amounts of (-) HCA, guarana extract, ma huang, and chromium (col. 1, lines 44, and 45).

None of the references disclosed *Garcinia cambogia* as a source of hydrocitric acid.

Dente teaches a daytime component of a weight loss system that comprises a fat burner, metabolism booster. Among the ingredients used in the invention are *ma huang* (col. 5, line 42), *guarana* (col. 5, line 51), and also *garcinia cambogia* fruit extract,

gymnema sylvestre leaf and chromium as chromium picolate (col. 7, lines 6-8). Dente also used vitamin B-6 (pyridoxine), col. 2, line 53.

Accordingly, it would have been obvious to one of ordinary skills in the art to combine Sundram, McCleary, and Dente to obtain a weight loss composition added to a salad dressing base. The skilled artisan would find it obvious also to add *guarana, mahuang*, and *garcinia camogia* because these ingredients are botanicals that would be audible and effective in weight loss compositions. The expected results would be a weight loss salad dressing nutrient.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-9, 12-23, and 25-30 are rejected on the ground of nonstatutory double patenting over claims 1-9, and 14-24 of U. S. Patent No. 6579866 (McCleary) since the

claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. As shown above McCleary's composition comprised the same ingredients of the instant application (hydroxycitric acid; an effective amount of carnitine; an effective amount of biotin; and an effective amount of one or more gluconeogenic substrates selected from the group consisting of aspartate, lactate, glycerol, and a gluconeogenic amino acid or alphaketo analogue thereof; the improvement comprising the addition of an effective amount of eicosapentanoic acid.) and also the same methods (method of losing weight, method of losing weight for a human following a dietary regiment involving glycemic index of less than 60, said human following exercise and aerobic training, a method for a human who donate blood so as to produce a fall in serum ferritin levels, and a method for a human follow a stress reduction program).

Accordingly, the instant application claims and McCleary disclosure are overlapping.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: ***

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

4. Claims 1-9, 11, 12-23, and 25-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9, 14-19, 21-25, 27, 29-32 of copending Application No. 10/987108.

The claims of the two applications are overlapping as reciting used for reducing the storage of lipids (weight loss) and comprising hydroxycitric acid, carnitine, biotin, gluconeogenic substrates, EPA, caffeine (guarana), nutritional supplement (which includes the same selection groups), the amounts and ratios recited in the two applications are similar and the methods recited are almost similar.

This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim 9/5/06

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER